

Exemptions to Permit Persons with a History of Viral (4/23/92)

Date: April 23, 1992

From: Director, Center for Biologics Evaluation and  
Research

Subject: Exemptions to Permit Persons with a History of Viral  
Hepatitis Before the Age of Eleven Years to Serve as  
Donors of Whole Blood and Plasma: Alternative  
Procedures, 21 CFR 640.120

To: All Registered Blood Establishments

This Memorandum responds to inquiries that the FDA has received for exceptions from certain donor suitability requirements set forth in 21 CFR 640.3(c)(1) and 640.63(c)(11). These two regulations preclude persons with a history of viral hepatitis, occurring at any age, from donating Whole Blood or Source Plasma.

On September 27, 1991, after discussion in a public meeting, the Blood Products Advisory Committee to the FDA recommended that the regulations referenced above be amended because they exclude a large number of suitable donors. The Committee further recommended that persons with a history of viral hepatitis, prior to 11 years of age, not be excluded from donating Whole Blood and Source Plasma.

In accordance with the recommendation of the Committee, FDA intends to propose amendments to the regulations referred to above. Until the regulations are amended, the FDA will consider procedures acceptable that permit a person with a history of viral hepatitis before the age of eleven years to serve as a donor of Whole Blood and Source Plasma. This exception to 21 CFR 640.3(c)(1) and 640.63(c)(11) is in conformance with 21 CFR 640.120, Alternative Procedures.